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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/501,932 | 10/18/2004 | Robert Eckl | 1529/2052 | 6789 |

29932 7590 08/07/2007
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| EXAMINER |
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CHUNG, SUSANNAH LEE

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| ART UNIT | PAPER NUMBER |
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1626

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| MAIL DATE | DELIVERY MODE |
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08/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/501,932 | ECKL ET AL. | |
| | Examiner | Art Unit | |
| | Susannah Chung | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/20/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending in the instant application.

Priority

This application is a 371 of PCT/EP03/01011, filed on 01/31/2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application nos. 10204072.9 and 10300049.6, filed in the German Patent Office on 01/31/2002 and 01/03/2003, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Response to Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 6/18/2007 is acknowledged. Specially, the election of species of the compound of Example 45, which is 2-(3-carbamimidoyl-phenylamino)-N-[4-(morpholin-4-carbonyl)-phenyl]-2-[2-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2-yloxy)-phenyl]-acetamide).

The reason for traversal is that corresponding claims were issued in European Patent EP 1470143 (in German) and that claims 19 and 20 are one inventive concept. Examiner acknowledges this, but respectfully disagree that all the claims have unity of invention (see previous office action). The Markush claims of claims 1-20 have unity of invention when a significant structural feature is identified which defines a contribution over the prior art. In the instant case, there is prior art, which breaks unity of invention and thus requires an election of an invention as a starting point in the examination process.

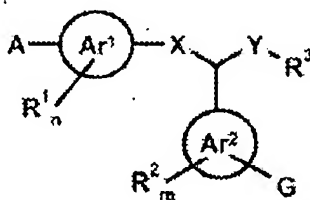
Therefore, for the above reasons, the requirement is still deemed proper and is therefore maintained.

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Scope of the Elected Invention

Claims 1-20 are pending in this application. Claims 16-18 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows:



Compounds of formula (I), , depicted in claim 1, page 2 of 9,

wherein:

Ar1 and **Ar2** are phenyl;

X is NH;

Y is NH-CO.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of the formula (I), wherein Ar1 and Ar2 are phenyl, X is NH, and Y is NH-CO, is not enabled for where Ar1 and Ar2 are not phenyl, X is not NH, and Y is not NH-CO. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

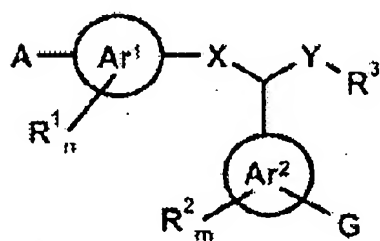
In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

- 1) the nature of the invention;
- 2) the state of the prior art
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the breadth of the claims;
- 7) the quantity of experimentation necessary; and ,
- 8) the level of skill in the art.

The Nature of the Invention

The nature of the invention is the compounds of formula (I),



The state of the prior art and the predictability or lack thereof in the art

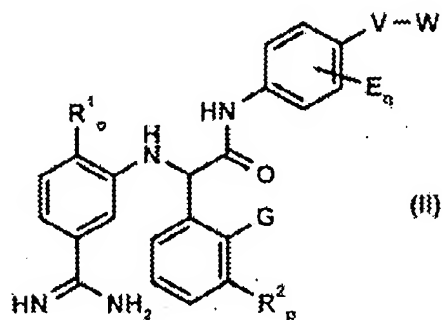
A Markush-type claim recites alternatives in a format such as “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925). The members of the Markush group (A, B, and C in the example above) ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. See MPEP § 808.02.

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The claims should contain subject matter which was described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Amount of direction/guidance & presence or absence of working examples

The only direction or guidance present in the instant specification is for compounds of formula (I), wherein Ar1 and Ar2 are phenyl, X is NH, and Y is NH-CO. The examples in the specification are only drawn to the preferred compound of formula (II),



, as shown on page 19 of the specification. (See Examples 1-63, pages 26-38, of the specification.)

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically; the instant claims include substituents or moieties not shown in the instant specification.

The quantity of experimentation necessary

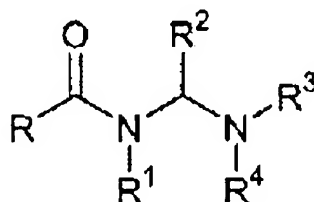
While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare all of the compounds of formula (I) as instantly claimed. The science of developing a target compound and libraries associated with that target compound is complicated and without guidance or working examples of the compounds, the claims lack enablement. The claims contain subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection can be overcome by deletion of the nonenabled moieties from claims 1-15, 19 and 20.

Conclusion

The closest prior art of record is Katritzky, et al., Monoacylaminals by the benzotriazole-assisted aminoalkylation of amides, *Synthesis*, Vol. October 1998, pages 1421-1423, which teach



similar amide compounds of formula (7), , wherein R, R2, and R3 are phenyl and R1 and R4 are hydrogen (see Compound of formula (7g) in the Table on page 1422). The difference between the compound of Katritzky and the instant application is the glycosal group that is present in the instant compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

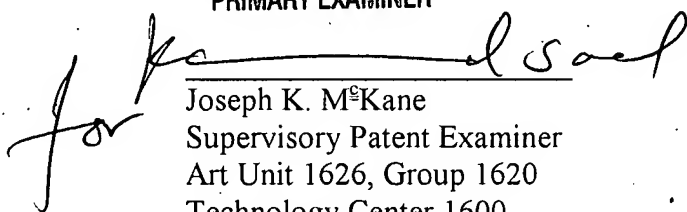
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

KAMALA A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read 'for Joseph K. McKane', is written over a horizontal line.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 2 August 2007